K083921

# 510 (K) SUMMARY

MAY 20 2009

**Applicant's Name and Address**

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**Contact Person**

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**1. Identification of device**

| | |
|---|---|
| Common Name: | Contact Lens |
| Trade Name: | SynergEyes™ SiH(petrafocon A hem-larafilcon A) Hybrid Daily Wear Lens |
| Classification: | Daily Wear Rigid Gas Permeable Contact Lens |
| Device classification: | Class II (21 CFR 886.5916) |

**2. Description of device**

The SynergEyes™ SiH (petrafocon A hem-larafilcon A) Hybrid Daily Wear Contact Lens is a combination of high Dk rigid gas permeable contact lens corneal optic portion surrounded by a soft hydrophilic silicone-hydrogel skirt (periphery) that straddles the limbus of the eye :

- in the power range of –20.00 to +20.00 diopters for sphere,
- cylinder powers up to 6.00 diopters for astigmatism
- with center thickness from 0.12mm to 0.30mm
- with base curves of 7.10mm to 9.00mm
- with diameter of 14.50mm
- Add Powers 1.00 to 4.00 (multifocal)

This lens material for the rigid portion is petrafocon A, an upgrade high Dk silicone base RGP material, lathe cut, surrounded by soft hydrophilic silicone-hydrogel copolymer (hem-larafilcon A), sterilized by means of e-beam sterilization. When placed on the human cornea, the SynergEyes™ SiH Hybrid Contact Lens acts as a refracting medium to focus light rays onto the retina. The device is available in the following indications: spherical, toric, and multifocal, with spherical or aspheric surfaces in violet visibility tint in the RGP center, and a UV absorber. This device is substantially equivalent to the SynergEyes™ A and M (paflufocon D hem-iberfilcon A) Hybrid Daily Wear Contact Lens predicate devices manufactured by the sponsor, SynergEyes, Inc.

The SynergEyes™ SiH Hybrid Daily Wear Contact Lens center is a highly oxygen permeable (Dk 130) rigid gas material of (petrafocon A). The soft skirt is comprised of silicone-hydrogel co-polymer (hem-larafilcon A) of 33% water and 73% polymer.

The junction between the rigid material and soft material is bound by a proprietary chemical bonding method.

**3. Intended use**

SynergEyes® SiH (petrafocon A hem-larafilcon A) Hybrid Contact Lenses for daily wear are indicated for use in the correction of hyperopic, myopic and astigmatic refractive error including presbyopia, in aphakic and not aphakic, non-diseased eyes. The lenses are indicated for daily wear for the correction of up to +20.00 and –20.00 D in eyes with astigmatism up to 6.00 D. For presbyopia, add powers between +1.00 and +4.00D. The lenses may be disinfected using only a chemical disinfecting system compatible with both hydrogel and rigid gas permeable lenses.

**4. Predicate device**

*For Design*: Predicate- K051035 SynergEyes™ A & M (paflufocon D hem-iberfilcon A) Hybrid Contact Lens

The SynergEyes™ SiH (petrafocon A hem-larafilcon A) Hybrid Contact Lens design is based on the SynergEyes™ (paflufocon D hem-iberfilcon A) Hybrid Contact Lens. The designs of both lenses are based on a rigid gas permeable center optic and a soft hydrogel skirt with a special proprietary bonding process to join the center and the peripheral portions at the junction of the optic edge where it joins the peripheral ring.

*For Material Similarities*: Predicate- K051035, K052560, K033919, K970746

The SynergEyes™ SiH (petrafocon A hem-larafilcon A) Hybrid Contact Lens has a rigid gas permeable center optic portion which is a high Dk (Dk 130) silicone based polymer (petrafocon A) surrounded by a silicone-hydrogel high Dk (Dk 84.2) soft skirt. The predicate lens, the SynergEyes™ A (paflufocon D hem-iberfilcon A) Hybrid Contact Lens has the center material-fluorosilicone acrylate, Paragon HDS material (Dk 100) permeability, surrounded by a hema-based polymer soft ring with Dk 9.1. The materials in both the subject device and predicate device are characterized as Group I low water, non-ionic in nature for their soft portions as the water content for the subject device is 33% and the predicate device is 25.0%. The water content for the rigid portion of both lenses is < 1%.

*For Physical and Optical Properties*: Predicate- K050135

The lens being cited as the predicate lens for the subject SynergEyes™ SiH (petrafocon A hem-larafilcon A) Hybrid Contact Lens is the SynergEyes™ A and M (paflufocon D hem iberfilcon A) Hybrid Contact Lens (K051035). The physical and optical properties that characterize both the subject and predicate device are shown in a side-by-side comparison chart. Properties such as oxygen permeability for both the center portion and peripheral skirt demonstrate the subject lens material to have a substantially higher permeability in both the RGP center and the soft skirt. Other properties that are compared for similarities and differences include refractive index, wetting angle, specific gravity, Shore Hardness, luminance transmittance, surface charge, surface treatment, water content, base curve, diameter, power range, chord diameter, UV additive.

**5. Characteristics**

The physical and dimensional characteristics of the SynergEyes™ SiH Hybrid Contact Lens are compared to the characteristics of the predicate device SynergEyes™ A and M Hybrid Contact Lens in the following table.

| Lens Characteristics | SynergEyes™ Hybrid Contact Lens K051035 | SynergEyes™ Hybrid Silicone/Hydrogel Lens (Subject Device) |
|---|---|---|
| Manufacturer | SynergEyes™ Inc. | SynergEyes, Inc. |
| Base Curves | 7.10-9.00mm | 7.10-9.00mm |
| RGP Center | 8.40mm | 8.40mm |
| Optic Zone Diameter | 7.80mm | 7.80mm |
| Lens Designs | Sphere, Aspheric, Front Surface Toric, Multifocal | Sphere, Aspheric, Front Surface Toric, Multifocal |
| Diameters: | 14.5mm | 14.5mm |
| Power Range | -20.00 to + 20.00D | -20.00 to +20.00 |
| Cylinder Range | 0.50 to 6.00D | 0.50 to 6.00D |
| Refractive Index (RGP) | RGP Center: 1.442 | RGP Center: 1.442 S/H Skirt: 1.435 |
| Wetting (Contact) Angle | RGP Center: 42° | RGP Center: 43.19° Soft Skirt: 29.40° |
| Specific Gravity (RGP) | 1.10 | 1.15±0.025 |
| Hardness Shore D | RGP: 74.8 Soft Skirt: | RGP: 76.0 Soft Skirt: Dry- 53.4 Hydrated- 8.9 (Shore A) |
| Indications for Use | Daily Wear | Daily Wear |
| UV Blocking | No | Yes |
| Material | RGP Center: Paflufocon D Soft Skirt: iberfilcon A (HEMA, MEMA) | RGP Center: petrafocon A Soft Skirt: hem-larafilcon A |
| Tint | Visibility Blue | Visibility violet |
| Soft Skirt Water Content | HEMA Skirt: 25% | S/H Skirt (Finished): 27.99% |
| Core (RGP) Water Content | < 1% | <1% |
| | | |

**6. Non clinical studies**

A battery of pre-clinical studies were performed on the subject device in accordance with the Guidance for Daily Wear Contact Lenses, May 1994.

Toxicology Studies were conducted under GLP and determined that the SynergEyes™ SiH (petrafocon A hem-larafilcon A) Hybrid Contact Lenses were biocompatible for the intended use in accordance with ISO 10993 Standard for the following tests:

- Cytotoxicity
- Acute Ocular Irritation
- Systemic Injection
- Guinea Pig Maximization
- 22 Day Ocular Irritation Study in Rabbits

Physico-chemical Studies including physical, optical and chemical properties as identified in Daily Wear Guidance for Contact Lenses demonstrated equivalent performance to the predicate device as witnessed in the chart listed above.

All pre-clinical and non-clinical studies demonstrated that the final lens subject to extractions and simulated in the above tests performed as expected with no findings related to safety that would be considered as unsafe for human use in the indications set forth for daily wear.

**8. Clinical data**

A three month daily wear clinical study was performed on the subject device. The study was a prospective, unmasked, open label study of a total of 98 subjects, in an approximate 2:1 ratio of test to control.

The test lens was the SynergEyes™ SiH (petrafocon A hem-larafilcon A) Hybrid Contact Lens, and the control lens was the SynergEyes™ A (paflufocon D hem-iberfilcon A) Hybrid Contact Lens. The study was performed at 8 investigational sites, and was designed to demonstrate that the test lens performed no worse than the control lens on a daily basis.

Eighty seven (87) subjects were randomized and dispensed lenses. The ratio of dispensed Test cohort subjects to dispensed Control cohort subjects was 1.81 to 1. The 90 day study period was completed by 73.2% (41 out of 56) dispensed Test cohort subjects and 87.1% (27 out of 31) dispensed Control cohort subjects.

Nineteen (19) subjects discontinued from the study (15 Test and 4 Control) with the most common reason for discontinuation reported as Subject Decision for the Test cohort (40% or 6/15) and Discomfort for the Control cohort (75% or 3/4). One Test cohort subject was discontinued for , Adverse Event and 1 Test cohort subject was discontinued for Positive Slit Lamp.

Reasons for Subject Discontinuation

| Reason for Discontinuation | Test Cohort | | Control Cohort | | Overall | |
|---|---|---|---|---|---|---|
| Adverse Event | 1 | 6.7% | 0 | 0.0% | 1 | 5.3% |
| Positive Slit Lamp | 1 | 6.7% | 0 | 0.0% | 1 | 5.3% |
| Comfort Related | 2 | 13.3% | 3 | 75.0% | 5 | 26.3% |
| Subject Decision | 6 | 40.0% | 1 | 25.0% | 7 | 36.8% |
| Protocol Violation | 2 | 13.3% | 0 | 0.0% | 2 | 10.5% |
| Unacceptable Visual Acuity | 2 | 13.3% | 0 | 0.0% | 2 | 10.5% |
| Lost to Follow-up | 1 | 6.7% | 0 | 0.0% | 1 | 5.3% |
| Total Discontinued | 15 | | 4 | | 19 | |

The demographics of the study subjects enrolled showed a slightly older population (average age: Control 40.6 / Test 37.3) with a greater proportion of females (female to male ratio: Control 3.9:1, Test 2.9:1) in the Control cohort as compared to the Test cohort. The majority (greater than 87%) of the subjects in the study were Caucasian for both cohorts.

A total of 5 adverse events were reported for 5 eyes during the study with 4 adverse events reported for the Test cohort and 1 adverse event reported for the Control cohort. Three (3) of the 5 adverse events (2 Test/ 1 Control) were reported as serious adverse events. Of the 2 Test cohort serious adverse events, 1 was a minor abrasion where the investigator noted a grade 1 (trace) infiltrate and 1+ cells in the anterior chamber, all of which had cleared in 4 days. The second serious adverse event was a microbial keratitis which was treated and cleared. The

single serious adverse event reported for the Control cohort was liver failure related to the use of homeopathic products.

Slit lamp findings reported during the study were compared between the Test and the Control cohorts and related to the baseline rates as well. Results of the slit lamp examinations showed the Test cohort eyes presenting with more staining overall when compared to the Control cohort examinations. All other slit lamp findings were reported a similar rates and severities when looking at the overall visit combined findings for both the Test and the Control cohorts.

Symptoms problems and complaints were compared between the Test and the Control cohorts and reviewed against the baseline proportions as well. The Test cohort eyes reported proportionately greater symptoms (1.1% for itching/burning to 16.1% for dryness) when compared to the Control cohort eyes except for excessive tearing (essentially equal) and variable vision (3.6% Control). Most of the differences in symptoms rates were small (3.7% or less) except for halos (8.6% Test) and dryness (16.1% Test).

Snellen visual acuity with contact lenses remained stable throughout the study for both the test and the control cohorts with only 2 Test cohort eyes and 2 Control cohort eyes reporting 2 or line drops of Snellen lens visual acuity with the contact lenses at the final visit.

Average daily wearing times were similar between the two cohorts and remained stable during the study and averaged between 11.6 to 13.0 hours per day for the Test cohort and 12.1 to 12.8 hours per day for the Control cohort.

Lens deposit evaluations and fitting evaluations provided similar results between the two cohorts. Lens replacements indicated that the Test lenses were replaced more frequently for parameter change and the Control lenses were replaced more frequently for discomfort.

In conclusion, the evaluation of primary safety variables and effectiveness of the test product SynergEyes™ SiH (petrafocon A hem-larafilcon A) Hybrid Contact Lens, support a conclusion of substantial equivalence between the test and control lens evaluated in the study.

**9. Risk and Benefits:**

The risks of the subject device are the same as those normally attributed to the wearing of RGP and soft (hydrophilic) contact lenses on a daily wear base. The benefits to the patient are the same as those for other RGP and soft (hydrophilic) contact lenses. The subject device has characteristics associated with it that should favor the risk benefit ratio in favor of the new device. Overall, the risks and benefits associated with daily wear contact lenses are the same as for other daily wear contact lenses and raise no additional concerns for safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 2009

SynergEyes, Inc.
c/o Richard E. Lippman, O.D., F.A.A.O.
Vice President for Ophthalmic Product Regulatory Affairs
R.P. Chiacchierini & Associates, LLC
15825 Shady Grove Road, Suite 30
Rockville, Maryland 20850

Re: K083921
Trade/Device Name: SynergEyes™ SiH (petrafocon A hem-larafilcon A) Hybrid Contact Lenses
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lens
Regulatory Class: Class II
Product Code: HQD
Dated: May 8, 2009
Received: May 11, 2009

Dear Dr. Lippman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

510(k) Number (if known) K083921

Device Name: SynergEyes® SiH (petrafocon A hem-larafilcon A)) Hybrid Contact Lens

Indication for Use

SynergEyes® SiH (petrafocon A hem-larafilcon A) Hybrid Contact Lenses for daily wear are indicated for use in the correction of hyperopic, myopic and astigmatic refractive error including presbyopia, in aphakic and not aphakic, non-diseased eyes. The lenses are indicated for daily wear for the correction of up to +20.00 and –20.00 D in eyes with astigmatism up to 6.00 D. For presbyopia, add powers between +1.00 and +4.00D. The lenses may be disinfected using only a chemical disinfecting system compatible with both hydrogel and rigid gas permeable lenses.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the –counter-use_____

(Division Sign-Off)
Division of Ophthalmic and Ear,
Nose and Throat Devices

510(k) Number K083921